K071491

OCT 10 2007

510 (k) Summary

Submitter:	ARROW International, Inc. 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	Karl Nittinger Regulatory Affairs Specialist Phone: 610-378-0131, ext. 3405 Fax: 610-478-3128 Email: karl.nittinger@arrowintl.com
Date summary prepared:	May 14, 2007
Device trade name:	Surgical Drape (21 CFR 878.4370, Product Code KKX)
Device common name:	Drape
Device classification name:	Surgical drape and drape accessories..
Legally marketed devices to which the device is substantially equivalent:	Medline Industries, Inc. Surgical Drape (K032666) and Pacon Manufacturing Corp. Surgical Drape (K850960)
Description of the device:	Arrow Surgical Drapes are sterile, disposable patient coverings for use in surgical procedures. They are composed of one or more of the following materials: Barrier, Absorbent, and Repellant materials. They may incorporate one or more fenestration openings for surgical site access and can also include medical grade patient fixation adhesive.
Indications for use:	Arrow Surgical Drapes are intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination..
Technological characteristics:	The proposed surgical drapes have the same technological design characteristics as the predicate devices.

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Performance tests:	The following tests were performed to demonstrate substantial equivalence: • Resistance to Liquid Penetration (Synthetic Blood): [AAMI PB70:2003 (ASTM F 1670)] • Resistance to Liquid Penetration (Hydrostatic Pressure): [AAMI PB70:2003 (AATCC 127)] • Spray Impact: [AAMI PB70:2003 (AATCC 42)] • Linting - Gelbo Flex Test: [ISO 9073-10:2004] • Tear Resistance: [ASTM F 5733] • Puncture Penetration: [ASTM F 1342] • Tensile Grab: [ASTM D 5034] • Flammability: [16 CFR Part 1610]
Assessment of non-clinical performance data:	The results of the bench tests demonstrate that Arrow's Surgical Drapes are safe, effective and perform favorably when compared to the predicate drapes.
Summary	Arrow International's Surgical Drapes have the same intended use as the predicate device. Based on the assessment of non-clinical performance data and the technological characteristic comparison, Arrow's Surgical Drapes are substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2007

Mr. Jeffrey D. Ravel
Senior Regulatory Affairs Manager
ARROW International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605-9607

Re: K071491
Trade/Device Name: Arrow Surgical Drape
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: September 27, 2007
Received: September 28, 2007

Dear Mr.Ravel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

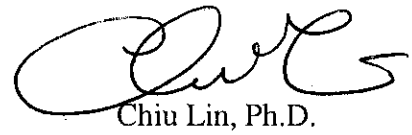
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K071491

Device Name: See attached list of product names

Indication For Use: Arrow Surgical Drapes are intended to be used as a protective patient covering to isolate a site of surgical incision from microbial and other contamination

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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Attachment 1: Drape Device Names subject to this submission

Drape Name	Drape Product Number	Size
Arrow Surgical Drape Clear Non-absorbable drape with Fenestration	D-60004-001	24 in x 30 in
Arrow Surgical Drape Non-absorbable drape	K-05600-035	12 in x 24 in
Arrow Surgical Drape Non-absorbable drape with Fenestration	D-05000-001	18 in x 26 in
Arrow Surgical Drape Absorbable drape with Fenestration	K-05501-003	24 in x 30 in
Arrow Surgical Drape Absorbable drape with Fenestration	D-05600-003	24 in x 36 in
Arrow Surgical Drape Absorbable drape with Multiple Fenestrations	D-45703-008	78 in x 99 in
Arrow Surgical Drape Absorbable drape with Clear Non-Absorbable Fenestrated Window	D-45703-009	68 in x 110 in
Arrow Surgical Drape Absorbable drape with Clear Non-Absorbable Fenestrated Window and Tear Line. Breathable in non-critical areas.	D-45703-013	54 in x 96 in
Arrow Surgical Drape Clear Non-absorbent Drape with Absorbent Edging, Fenestration and Tear Line	K-12703-001	21 in x 36 in